

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/255, 655 02/23/99 VIGH

M 02405.0167

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HM12/0522

EXAMINER

OWENS, JR, H

ART UNIT	PAPER NUMBER
	9 1623

DATE MAILED:

05/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/255,655	Applicant(s) Vigh et al.
Examiner Howard Owens	Group Art Unit 1623

Responsive to communication(s) filed on _____.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-12 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-12 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Arguments

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The following is in response to the amendment filed 3/01/00:

An action on the merits of claims 1-12 is contained herein below.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objection to the Specification

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Objection to the specification has been overcome through applicant's amendment.

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35 USC § 103

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Applicant's arguments filed 3/01/00 in response to the rejection of claims 1- 12 under 35 U.S.C. 103(a), have been fully considered but they are not persuasive. The rejection of claims 1-12 under 35 U.S.C. 103(a) is maintained for the reasons of record.

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The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

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In the case of the instant application, the prior art cited has set forth that monosaccharides such as D-tagatose serve as a substrate for the production of Short Chain Fatty Acids such as butyrate and also allow for the growth of commensalistic indigenous flora such as *Lactobacilli*. Therefore, it would have been *prima facie* obvious to use D-tagatose or any other saccharide which may be positively fermented by indigenous microflora of the human large intestine in a method for inducing production of butyrate or stimulating the growth of *lactobacilli* and lactic acid bacteria. Applicant acknowledges that "an increased ingestion of malabsorbed or undigested carbohydrate gives a general stimulation of colon fermentation and thus a general stimulation of production of SCFAs including butyrate", however applicant claims that D-tagatose is unique in its ability to selectively induce production of butyrate even though the prior art (Zehner) teaches that D-tagatose is slowly degraded by indigenous microflora such as *Lactobacillus casei* and is metabolized at a small extent by the body; moreover, that unabsorbable sugars such as D-tagatose are subject to fermentation in the human colon (col.1, lines 60-66). Given the characteristics of D-tagatose and the production of SCFAs from monosaccharides as set forth by the prior art, one of skill in the art would be provided with a reasonable expectation of success in the use of D-tagatose to induce production of butyrate and stimulate the growth of *lactobacilli*.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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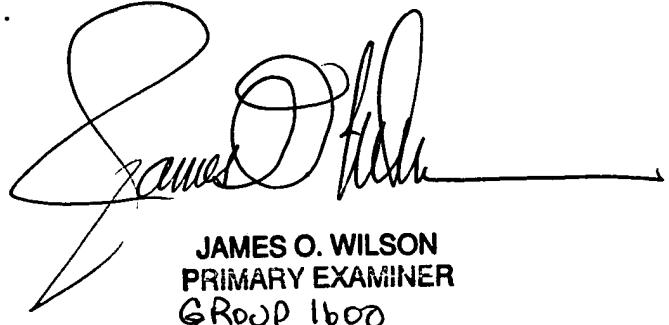
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Howard Owens

Group 1623



JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600